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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,477	01/09/2007	Masao Sudoh	Q94121	2361

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EXAMINER	
KATAKAM, SUDHAKAR	
ART UNIT	**PAPER NUMBER**
1621	
MAIL DATE	**DELIVERY MODE**
11/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,477	SUDOH ET AL.	
	Examiner	Art Unit	
	Sudhakar Katakam	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31,33 and 34* is/are pending in the application.

4a) Of the above claim(s) *18-19 and 29-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,20-28,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Restriction

1. Applicant's election of claims 1-17, 20-28 and 33-34 in the reply filed on 22nd August 2007 is acknowledged.

Claims 18-19, and 29-31 are withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 22nd August 2007.

Information Disclosure Statement

2. The examiner has considered applicant's Information Disclosure Statements of 3rd April 2007. Please refer to the signed copies of the PTO-1449 forms attached herewith.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 17 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by **Hasegawa et al** (Bull.Chem.Soc.Jpn. 2000, 73, 423-428) or **JP 8291106**.

The instant claims are drawn to a medicament comprising (2R)-2-propyloctanoic acid or salt thereof and a basic metal ion.

Hasegawa et al disclose an optically active (R)-2-propyloctanoic acid, valuable therapeutic agent for neurodegenerative diseases such as Alzheimer's disease (see equation 1 in page 423 and introduction).

JP 8291106 also discloses a salt of optically active (2R)-2-propyloctanoic acid (see Abstract).

The compound will inherently have the same physico-chemical properties of its salt and hence it meets the instant claims. Please note that the most common salt of medicaments comprises basic metal ions such as sodium, potassium or magnesium etc.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-17, 20-28, and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hasegawa et al** (Bull.Chem.Soc.Jpn. 2000, 73, 423-428) or **JP 8291106** in view of **Ohuchida et al** (US 6,201,021).

The instant claims are drawn to a medicament comprising (2R)-2-propyloctanoic acid or salt thereof and a basic metal ion. The claims are further limited to the scope of the metal salt, pH, concentrations of the components in the medicament.

Hasegawa et al disclose an optically active (R)-2-propyloctanoic acid, valuable therapeutic agent for neurodegenerative diseases such as Alzheimer's disease (see equation 1 in page 423 and introduction).

JP 8291106 also discloses a salt of optically active (2R)-2-propyloctanoic acid for use in treating neurodegenerative disorders (see Abstract, translation is pending, and attached Derwent abstract).

The difference between the instant claims and the references is that the references teach the compound or its salt and silent on the scope of metal slats, pH and the concentration of the components in the medicament.

The salts of (2R)-2-propyloctanoic acid are known in the art. Also the process of making salt and adjusting pH accordingly is also known in the art. Please note that the most common salt of medicaments comprises basic metal ions such as sodium, potassium or magnesium etc.

Ohuchida et al teach a suitable basic metal ions for the preparation of salts of pentanoic acid derivatives [col.17, lines 1-24].

It would have been obvious to a person of ordinary skill in the art at the time of the invention to use the teachings of references and known methods to make the salts from the art, and to make the instant applicants medicament with a reasonable expectation of success. One would have been motivated to arrive instant claims because **Hasegawa et al** teach "preparation of (2R)-2-propyloctanoic acid" and this compound is a therapeutic agent of neurodegenerative diseases such as Alzheimer's disease. Therefore, one would combine the teachings of the references in order to provide for a medicament mixing the (2R)-2-propyloctanoic acid with a basic metal ion in order to provide for better stability of the composition in storage. For the foregoing reasons the instant claims are made obvious.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-17, 20-28 and 33-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending U.S. Application No. 10/574,476.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

The instant claims are drawn to a medicament comprising (2R)-2-propyloctanoic acid or salt thereof and a basic metal ion.

The copending application claims are drawn to an infusion preparation comprising (2R)-2-propyloctanoic acid or a salt thereof and a basic metal ion.

The difference between the instant claims and the copending application is that the instant claims are drawn to a composition of (2R)-2-propyloctanoic acid or a salt thereof and a basic metal ion, whereas the copending application claims are drawn to process of making the composition which comprises (2R)-2-propyloctanoic acid or a salt and a basic metal ion.

It would have been obvious to one of ordinary skill in the art, at the time of invention was made, to start with the copending application teachings to get the instants' applicants' composition with a reasonable expectation of success. The difference does not constitute a patentable distinct, because the process of making the composition also results in its composition and hence the present invention simply fall within the scope of copending application, since similar components and conditions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not been patented yet.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sudhakar Katakam
Patent Examiner
Nov 9, 2007

PETER O'SULLIVAN
PRIMARY EXAMINER
GROUP 1200